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1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,826

Applicant(s)

DUWEING ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55,59,60,62-91 and 95-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55,59,60,62-73,90 and 91 is/are allowed.
- 6) ☒ Claim(s) 74-89 and 95-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The response filed July 22, 2004 has been entered.

Claims 1-54, 56-58, 61, 92-94 and 100 are cancelled.

Claims 55, 59-60 and 62-73 are allowed.

Claims 90-91 are currently amended.

Claims 55, 59-60, 62-91 and 95-99 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Drawings

The drawing filed July 22, 2004 is accepted by the Examiner.

Claim Rejections - 35 USC § 112

Claims 96-99 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed April 19, 2004.

Applicant's arguments filed July 22, 2004, have been fully considered but they are not persuasive.

Applicant points to the disclosure of an experiment at page 44 of the specification wherein one aliquot of *B. vulgaris* cells had been exposed to control medium and another

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aliquot of *B. vulgaris* cells had been exposed to control medium supplemented with 125 mM NaCl. Applicant points out that twenty-four hours after the transformation of the cells of both aliquots with a DNA construct comprising the isolated *B. vulgaris* V-ATPase subunit c, isoform 2 promoter, operatively linked with a heterologous luciferase gene, the luciferase activity was determined to be 1.11 and the luciferase activity for the aliquot of cells exposed to control medium supplemented with 125 mM NaCl was determined as 2.17. Applicant maintains that this experiment clearly proves that the incubation of *B. vulgaris* cells in a medium containing 125 mM NaCl for 24 hours (which corresponds to "salt stress" conditions) leads to an approximately 2-fold increase of the expression of a heterologous gene that is controlled by the *B. vulgaris* V-ATPase promoter, subunit c, isoform 2 (here luciferase) and that the specification thus unambiguously discloses the strong effect of salt stress on the function of the isolated *B. vulgaris* V-ATPase subunit c, isoform 2 promoter. (reply pages 2-3).

The outstanding written description rejection was not predicated on the failure to describe the effect of salt stress on the function of the isolated *B. vulgaris* V-ATPase subunit c, isoform 2 promoter. As set forth at pages 3-4 of the office action mailed April 19, 2004, the outstanding written description rejection was predicated on the failure to describe transformed plant cells, protoplasts or plants which are resistant to stress or salt stress as a result of the expression of the DNA construct. The outstanding written description rejection was also predicated on the failure to describe which heterologous genes, when expressed under the control of the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO: 1 in a plant cell, protoplast or plant, would confer to a plant cell, protoplast or plant tolerance to stress or to salt stress. Neither the

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specification nor the prior art describes the luciferase reporter gene as having the capacity to confer to a plant cell, protoplast or plant tolerance to stress or to salt stress.

Applicant additionally maintains that the specification provides sufficient guidance for a person skilled in the art with respect to which stress to employ and with respect to how much stress to employ in order to upregulate the expression of the heterologous gene of the DNA construct, and that claims 95-99 thus should clearly meet the enablement requirement under 35 USC 112, first paragraph. Applicant also argues that the examiner's requirement for a "representative number of species" falling within the scope of the claimed genus of plant cells, protoplasts, and plants" is not supported by any specific reasons. Applicant points out that there is a burden on the examiner to present reasons to doubt the objective truth of the generic statements throughout the specification. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). Applicant maintains that the present specification enables the practice of a broad invention, and that broad inventions can be defined only by broad claims. Applicant maintains that it is not incumbent on an applicant who has made a broad process invention and supported it by an adequately broad disclosure to demonstrate the operativeness of every substance falling within the scope of the broad claims to which he is entitled. *In re Sarett*, 327 F.2d 1005, 140 USPQ 474, 486 (CCPA 1964). (reply page 3).

Applicant's arguments are not directed to the substance of the outstanding written description rejection as discussed above. Furthermore, the written description and enablement requirements are separate requirements under 35 USC 112, first paragraph. Accordingly, the assertion that claims 95-99 should clearly meet the enablement

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requirement, and Applicant's reliance on case law directed to meeting the enablement requirement under 35 USC 112, first paragraph (*In re Marzocchi*), are not germane to the outstanding written description rejection. Additionally, the written description and definiteness requirements are separate requirements under 35 USC 112, first paragraph and 35 USC 112, second paragraph, respectively, such that Applicant's reliance on case law directed to meeting the definiteness requirement under 35 USC 112, second paragraph (*In re Sarett*) is not germane to the outstanding written description rejection.

Claims 74-89 and 95-99 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO: 1, a method for expressing a heterologous gene in response to salt stress, and a method for producing a recombinant protein, does not reasonably provide enablement for a method for expressing a heterologous gene in response to other stresses, or for plants, plant cells or protoplasts which are resistant to biotic or abiotic stress, or salt stress, for the reasons of record set forth in the office action mailed April 23, 2002.

Applicant's arguments filed July 22, 2004, have been fully considered but they are not persuasive.

Applicant traverses the rejection, and points out that claims 74-89 and 95-99 are all dependent on the previously amended claim 55, which, after the present amendment, is specifically directed to DNA constructs comprising the *B. vulgaris* promoter subunit c, isoform 2, operatively linked with a heterologous gene. Applicant maintains that specific examples of DNA constructs comprising promoters other than the *B. vulgaris* promoter

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subunit c, isoform 2, should not be required. Applicant argues that any such additional promoters which interfered with the function of the recited promoter would not come within the claims because they would be considered inoperative species. Applicant points out that it is not the function of the claims to specifically exclude impossible or inoperative species. *In re Anderson*, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1973). Applicant maintains that the generic concept of additional promoters is disclosed in the original specification at page 6. Applicant further maintains that *In re Marzocchi*, supra and *In re Anderson*, supra, are relevant to this rejection also. Applicant asserts that the examiner has set forth no reasons to doubt the generic disclosure and has suggested no specific additional promoters that would interfere with the function of the recited promoter. Also, the examiner has suggested no claim amendment which in his opinion would overcome this rejection. See MPEP 2173.02. (reply pages 3-4)

The Examiner acknowledges Applicant's point that claims 74-89 and 95-99 are all dependent on the previously amended claim 55, which, after the present amendment, is specifically directed to DNA constructs comprising the *B. vulgaris* promoter subunit c, isoform 2 set forth in SEQ ID NO: 1, operatively linked with a heterologous gene, and agrees that specific examples of DNA constructs comprising promoters other than the *B. vulgaris* promoter subunit c, isoform 2 set forth in SEQ ID NO: 1, should not be required to meet the enablement requirement.

The Examiner maintains, however, that the dependence of claims 74-89 and 95-99 on claim 55 does not enable the full scope of the claimed invention, because the outstanding scope of enablement rejection was not solely predicated on the failure of the specification to provide sufficient guidance with respect to which promoter species to

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employ to practice the claimed invention. As set forth at pages 6-7 of the office action mailed April 23, 2002, the outstanding enablement rejection was also predicated on the failure of the specification to provide sufficient guidance with respect to controlling the expression of the heterologous gene using any unspecified type of stress. As set forth at pages 7-8 of the office action mailed April 23, 2002, the outstanding enablement rejection was additionally predicated on the failure of the specification to provide sufficient guidance with respect to making transgenic plant cells and plants that are resistant to any unspecified type of stress or that are resistant to salt stress. Applicant's response to the outstanding scope of enablement rejection does not explicitly address these issues. Applicant's failure to explicitly address these issues in response to response to the outstanding rejection notwithstanding, the Examiner notes the experiment at page 44 of the specification referred to by Applicant in the response to the written description rejection, and the Examiner directs Applicant's attention to the current enablement rejection, which acknowledges the enablement of salt stress for controlling the expression of the heterologous gene operatively linked to the *B. vulgaris* subunit c, isoform 2 promoter of SEQ ID NO:1.

With respect to Applicant's reliance on *In re Marzocchi* and Applicant's assertion that the examiner has set forth no reasons to doubt the generic disclosure, the Examiner maintains that several reasons were set forth in the office action mailed April 23, 2002.

Applicant's attention is directed in particular to Page 6 of the action which indicated that "While one of skill in the art could readily transform plants with the disclosed promoter fragment and express a heterologous gene, it would require undue experimentation for one of skill in the art to determine how to select and use a biotic or

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abiotic stress to control the expression of the heterologous gene, because the specification provides no guidance with respect to which stress to employ, or with respect to how much stress to employ, so that the expression is subject to the control of one skilled in the art”.

Applicant’s attention is also directed in particular to pages 6-7 of the action which indicated that “Even though the specification discloses salt and wounding stress induction of RNA expression from the *B. vulgaris* V-ATPase subunit c isoform 2 gene *in situ*, it does not necessarily follow that RNA expression from any isolated fragment of that promoter will also be induced by salt and wounding stress, or other types of stress. For example, if the isolated promoter fragment lacks the stress inducible structural elements possessed by the native promoter, the isolated promoter fragment will not be stress inducible. Likewise, since different types of structural elements within a promoter may mediate different types of stress induction, a promoter induced by one type of stress, such as salt stress, may not be inducible by another type of stress, such as heat stress. The specification does not disclose the number and nature of such elements, if any, that are in the elected promoter.”.

Applicant’s attention is additionally directed in particular to pages 7-8 of the action which indicated that “While one of skill in the art could readily transform plants with the disclosed promoter fragment and express a heterologous gene, it would require undue experimentation for one of skill in the art to determine which heterologous gene to express such that the resultant transgenic plants are resistant to biotic or abiotic stress or salt stress. The specification does not disclose the expression of any specific heterologous gene whose expression confers resistance to biotic or abiotic stress or salt stress. The

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specification provides no guidance with respect to whether and under what conditions any particular stress resistance gene might be expressed from the elected promoter such that the resultant transgenic plants are resistant to biotic or abiotic stress or salt stress. For example, it may be necessary to express a particular stress resistance gene at particular level of expression and/or in a particular tissue in order to confer stress resistance. If the elected promoter were unable to express a particular stress resistance gene at the required level and/or in the relevant tissue, the resultant transgenic plants would not be resistant to biotic or abiotic stress or salt stress, notwithstanding the ability of the elected promoter to function as a promoter per se.

The Examiner here notes the assertion made by Applicant in the response to the written description rejection, that the specification provides sufficient guidance for a person skilled in the art with respect to which stress to employ and with respect to how much stress to employ in order to upregulate the expression of the heterologous gene of the DNA construct, and that claims 95-99 thus should clearly meet the enablement requirement under 35 USC 112, first paragraph. The Examiner first maintains that the disclosure that salt stress induces expression from the claimed promoter fragment does not limit the term "stress" as it is used in the rejected claims. The disclosure of a single type of stress that induces expression from the claimed promoter fragment does not provide guidance with respect to which other stresses would induce expression from the claimed promoter fragment and which would not, or with respect to how to use other stresses to induce expression from the claimed promoter fragment. Furthermore, the disclosure that salt stress induces expression from the claimed promoter fragment does

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not provide guidance with respect to which heterologous genes to express from the claimed promoter to confer stress resistance to a plant cell or plant transformed therewith.

With respect to Applicant's reliance on *In re Anderson*, the Examiner acknowledges that it is not the function of the claims to specifically exclude impossible or inoperative embodiments. The Examiner maintains, however, that the specification does not provide sufficient guidance for one skilled in the art to be able to discriminate between the operative and inoperative embodiments encompassed by the claims.

With respect to Applicant's assertion that the examiner has suggested no claim amendment which in his opinion would overcome this rejection, as suggested by MPEP 2173.02, the Examiner maintains that MPEP 2173.02 concerns the requirement for definiteness under 35 USC 112, second paragraph, and is therefore not germane to the outstanding enablement rejection, which was made under 35 USC 112, first paragraph.

Claim 95 remains rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, for the reasons of record set forth in the office action mailed April 19, 2004.

Applicant's arguments filed July 22, 2004, have been fully considered but they are not persuasive.

Applicant argues that the examiner has provided no authority for his apparent position that all of the steps of a claimed process are required to be recited. Applicant also asserts that to further prosecution of the application the relevant claims have been amended to include the steps of transforming and expressing. (reply pages 4-5)

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The Examiner maintains that authority for this position was provided. Applicant's attention is directed to page 8 of the office action mailed April 23, 2002, which provides the text of the second paragraph of 35 USC 112, second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection is maintained with respect to claim 95 because claim 95 has not been amended. Claim 95 is missing the essential step of expressing a gene. In the absence of gene expression, the method of claim 95 will not result in the expression of a gene. Furthermore, the claimed method does not result in the expression of a gene as set forth in the preamble.

Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 95 is indefinite in depending from cancelled claim 93.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 55, 59, 60, 62-73 and 90-91 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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